K050332



MAY 27 2005

## ADMINISTRATIVE INFORMATION


Manufacturer Name: MAST Biosurgery, Inc.
6749 Top Gun Street, Suite C
San Diego, CA 92121

Official Contact: Kenneth K. Kleinhenz
Regulatory Affairs
Telephone (858) 458-0900
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## DEVICE NAME

Classification Name: Surgical Mesh, Polymeric

Trade/Proprietary Name: Surgi-Wrap MAST Bioresorbable Sheet

## ESTABLISHMENT REGISTRATION NUMBER

3004661493

## DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 878.3300, Surgical Mesh are polymeric screens intended to be implanted to reinforce soft tissues. These devices are classified as Class II. Surgical Mesh have been assigned Product Code FTL.

## INTENDED USE

The Surgi-Wrap MAST Bioresorbable Sheet is to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse, repair, reconstruction of the pelvic floor and sacral colposuspension. The resorbable Protective Film minimizes tissue attachment to the device in case of direct contact with the viscera. The device is indicated for open and laparoscopic procedures. Laparoscopic procedures are limited to sizes from 0.02mm – 0.2mm in thickness.

## DEVICE DESCRIPTION

### Design Characteristics

MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet is a resorbable implant in sheet form manufactured from polylactic acid (PLA). The Surgi-Wrap MAST Bioresorbable Sheet can be cut with scissors to the desired shape and size. The Surgi-Wrap MAST Bioresorbable Sheet Sheet is fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation. The Surgi-Wrap MAST Bioresorbable Sheet can be used either alone or in conjunction with soft tissue fixation devices such as resorbable sutures, which can also serve to fixate the Surgi-Wrap MAST Bioresorbable Sheet and prevent dislocation. The Surgi-Wrap MAST Bioresorbable Sheet may be used in conjunction with various MAST Biosurgery Class I manual instruments (forceps, scissors, clamps, etc.).

The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet is provided in various shapes such as rectangles, ovals, and circles and will be provided in other shapes and sizes as needed for particular surgical procedures. The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet is provided in sheets of 25mm x 25mm to 500mm x 500mm and will be provided in other shapes and sizes as needed for particular surgical procedures. The thickness of the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet ranges from 0.02 mm to 1.0 mm according to the region to be treated. The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet is provided in solid sheets. The borders of the sheets may be aligned with holes to attach suture material.

### Material Composition

The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet is fabricated from polylactic acid (PLA).

### In Vitro Testing

The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures. Therefore, testing was performed to determine the effect of prolonged heating in saline at 60°C on inherent viscosity. The testing demonstrates that viscosity stayed within an appropriate range over 120 minutes. The relatively brief exposure anticipated during the surgical preparation of MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet is not expected to have a significant effect on its mechanical properties.

Aging testing was performed on MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet. Testing demonstrated that the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet is strong enough for the indications for use.

Mechanical testing was performed on the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet which determined the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

**In Vivo Testing**
Animal studies were conducted to demonstrate safety and efficacy of the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet material. The animal studies demonstrated that the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet materials are safe and efficacious for the indications for use.

## EQUIVALENCE TO MARKETED PRODUCT

The MAST Biosurgery SurgiWrap MAST Bioresorbable Sheet shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: MacroPore Surgi-Wrap MAST Bioresorbable Sheet, MacroPore SurgiWrap (TS), GFE Medizintechnik TiMESH, and the InjecTx Biosling; Class II medical devices that were cleared for marketing in the United States under K031955, K012025, K031225, and K010533 respectively.

**Indications For Use**
The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet shares identical indications for use principles with the predicate devices as the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet and the predicate devices are indicated for the same surgical procedures.

**Design and Materials**
The physical designs of MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet and the predicate devices (MacroPore Surgi-Wrap MAST Bioresorbable Sheet, MacroPore SurgiWrap (TS), and the InjecTx Biosling) are substantially equivalent, consisting of thin semi-rigid sheets that are fabricated from resorbable materials. The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet and the MacroPore Surgi-Wrap MAST Bioresorbable Sheet and MacroPore Surgi-Wrap (TS) predicate device are identical in fit, form, and function as all devices are manufactured with the same process and fabricated from the identical raw material. The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet and the predicates also share design features of allowing for contouring. The MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet and the MacroPore SurgiWrap predicates are fully contourable when heated to approximately 55°C. The thickness, shapes, and sizes of the MacroPore SurgiWrap predicates and the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet are substantially equivalent as they are identical ranging in sizes from 25mm x 25mm to 500mm x 500mm with thickness ranges from 0.02mm to 1.0mm. The dimensions of the GFE Medizintechnik TiMESH predicate devices are also comparable to the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet as both devices are provided in rectangular sheets that are several centimeters in size. The mechanical characteristics of the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet are substantially equivalent to the predicate devices. In addition to physical characteristics, both the predicate device and the MAST Biosurgery Surgi-Wrap MAST Bioresorbable Sheet can be cut to specific shapes and sizes by the end user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2005

Mr. Kenneth K. Kleinhenz
Regulatory Affairs
Mast Biosurgery Incorporated
6749 Top Gun Street, Suite C
San Diego, California 92121

Re: K050332
Trade/Device Name: Surgi-Wrap MAST Bioresorbable Sheet
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: April 27, 2005
Received: April 29, 2005

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050332

# Indications for Use

**510(k) Number : K050332**

Device Name: **Surgi-Wrap MAST Bioresorbable Sheet**

**Indications for Use:**

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Restorative
Devices

K050332